

## **DETAILED ACTION**

### ***Notice to Applicant***

This communication is in response to the communication filed 05/12/2009.

Pending claim(s): 1-7. New claim(s): 2-7. Amended claim(s): 1.

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ashley N. Lindsey on 08/17/2009.

The application has been amended as follows:

1-7. (Cancelled)

8. (New) Computer-storage media having computer-executable instructions embodied thereon that, when executed, cause a machine to perform a method for effecting a controlled, recurring assessment of a care episode and service utilization patterns associated with a locale, the locale including a plurality of corresponding institutions, the method comprising the steps of:

(a) receiving a population dataset comprising one or more population data records, wherein each population data record describes a population or population

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density for a unique geographic location, and wherein none of the described geographic locations overlaps;

(b) receiving an encounter dataset comprising one or more encounter data records, wherein each encounter data record describes a distance, measured in physical distance or time, between:

(1) an inception of a clinical event or need for care; and

(2) provision of care at an appropriate location of service;

(c) receiving one or more statistical parameters;

(d) for each population data record, statistically power transforming the data contained in the respective population data record using the one or more statistical parameters to generate a corresponding transformed population data record;

(e) for each encounter data record, statistically power transforming the data contained in the respective encounter data record using the one or more statistical parameters to generate a corresponding transformed encounter data record;

(f) for each transformed population data record, standardizing each transformed population data record using the set of all transformed population data records as a first baseline to generate a corresponding standardized transformed population data record;

(g) for each transformed encounter data record, standardizing each transformed encounter data record using the set of all transformed encounter data records as a second baseline to generate a corresponding standardized transformed encounter data record;

(h) linking each standardized transformed encounter data record to a corresponding standardized transformed population data record;

(i) for each standardized transformed encounter data record, calculating a distance index based on the respective standardized transformed encounter data record and the corresponding standardized transformed population data record;

(j) for each distance index, standardizing the respective distance index using the set of all distance indices as a third baseline to generate a standardized distance index;

(k) assessing the departure of the set of one or more standardized distance indices from a standard normal statistical distribution;

(l) if the assessment in step (k) conforms to a predetermined threshold, identifying the set of standardized distance indices as the set of optimized distance indices;

(m) else if the assessment in step (k) does not conform to the predetermined threshold, changing the one or more statistical parameters and repeating steps (d-k);

(n) identifying one or more health care providers;

(o) for each optimized distance index, risk-adjusting the respective optimized distance index and assigning the risk-adjusted optimized distance index to a single health care provider chosen from the set of one or more health care providers based on the geographic location served by the health care provider; and

(p) for each health care provider, generating a report by aggregating any risk-adjusted optimized distance indices assigned to the respective health care provider,

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wherein the report assesses for the corresponding geographic location served by the health care provider:

- (1) quality of health services;
- (2) under-resourced health care needs;
- (3) prevention of medical complications; and
- (4) comparative performance of the corresponding health care providers to

other health care providers.

### ***Response to Amendment***

As per the Office Action mailed 11/12/2008:

The rejection of claim 1 under 35 USC 101 is hereby withdrawn in view of Examiner's cancellation of claim 1.

### ***Statutory Subject Matter - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As per claim 8, this claim recites a computer readable medium containing thereon software capable of controlling the operations of a computer.

Examiner considers this claim to recite a manufacture in accordance with MPEP 2106.01.

Therefore, claim 8 is found to be directed towards statutory subject matter.

***Written Description - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MPEP 2163(I)(B) reads as follows:

“While there is no *in haec verba* requirement, **newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure**”.

MPEP 2163.02 reads as follows:

“An applicant shows possession of the claimed invention by **describing the claimed invention with all of its limitations** using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.

*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)”.

To preserve Applicant’s priority claim, support for the pending claim(s) may be found in the specification in provisional application 60446692 as originally filed on 02/11/2003.

Claim 1 recites:

“Computer-storage media having computer-executable instructions embodied thereon that, when executed, cause a machine to perform a method for effecting a

controlled, recurring assessment of a care episode and service utilization patterns associated with a locale, the locale including a plurality of corresponding institution”.

On page 28-39 of the specification, Applicant provides source code for the claimed method. Therefore, clear support exists for “computer-storage media” containing thereon software capable of controlling execution of a computer.

Claim 1 further recites:

“(a) receiving a population dataset comprising one or more population data records, wherein each population data record describes a population or population density for a unique geographic location, and wherein none of the described geographic locations overlaps;”

The specification discloses (page 5-6):

[0015] A preferred embodiment of the present invention for the United Kingdom uses the “Postcode District” (or PD), or, in another preferred embodiment for the United States, the present invention uses the 3-digit zip code or county FIPS (Federal Information Processing Standards) to identify geographic localities from which the captured cases originated. In the preferred embodiment for the U.K., the originating geographic locality is not identified with respect to the SHA and Hospital Trust geographic boundaries, which are not where the people live nor where the care episodes start out necessarily. The PD is the first part of a U.K. Postcode before the space in the Postcode and typically comprises two to four characters. It is used to specify the town or district to which a letter or package is to be sent for further sorting. Once the PD is received, the present invention obtains the census population and latitude-longitude GIS (Geographic Information System) coordinates for the centroid of each PD.

The specification clearly discloses that the population data is received for distinct geographic locations that do not overlap, e.g. unique postal codes.

Claim 1 further recites:

“(b) receiving an encounter dataset comprising one or more encounter data records, wherein each encounter data record describes a distance, measured in physical distance or time, between:

- (1) an inception of a clinical event or need for care; and
- (2) provision of care at an appropriate location of service;”

The specification discloses (page 5):

The distance index set forth in the present invention can utilize distance either measured in miles (kilometers) or elapsed-time minutes from the inception of a clinical event or need for care, until the provision of care at an appropriate location of service. (The minutes or geographical distance are statistical distributions, measurable and aggregated, in preferred embodiments, on a monthly or quarterly basis, from cases accruing in each catchment area.)

The specification discloses that the distance may be measured in physical distance or time.

Claim 1 further recites:

“(c) receiving one or more statistical parameters;”

The specification discloses (page 8):

The Anderson-Darling metric is calculated for the distribution of distance values, to assess departure from a normal curve, and if the value of  $A_n^2$  is greater than or equal to  $A_{n,\alpha}^2$  then the null hypothesis of normality is rejected and values of  $\lambda_1$  and  $\lambda_2$  are incremented and the loop processing is repeated. Iterations continue until  $A_n^2$  is less than  $A_{n,\alpha}^2$ .

According to the specification, the loop uses a control parameter to determine if the value is satisfied. This control parameter provides support for “one or more statistical parameters”.

Claim 1 further recites:

“(d) for each population data record, statistically power transforming the data contained in the respective population data record using the one or more statistical parameters to generate a corresponding transformed population data record;

(e) for each encounter data record, statistically power transforming the data contained in the respective encounter data record using the one or more statistical parameters to generate a corresponding transformed encounter data record;”

The specification discloses (page 7):

[0019] For each care episode and the person or family to which it pertains, a power transform is used for both the P-variable of the locale in which the episode originates, and for the D-variable. In the present invention, the Box-Cox transform involves iterative determination of optimal values for  $\lambda_1$ , the power to which each  $D_i$  for the  $i^{\text{th}}$  care episode is raised, and  $\lambda_2$ , the power to which each  $P_j$  for the  $j^{\text{th}}$  county or catchment area is raised. The transformation is expressed as:

$$D_i = \text{sign}(\lambda_1) \frac{D_i^{\lambda_1}}{\text{std}(D^{\lambda_1})}$$

$$P_j = \text{sign}(\lambda_2) \frac{P_j^{\lambda_2}}{\text{std}(P^{\lambda_2})}$$

where  $\text{std}(P^{\lambda_2})$  is the sample standard deviation of  $P_1^{\lambda_2}, \dots, P_n^{\lambda_2}$  and similarly for  $D_i^{\lambda_1}$ .

The specification discloses that the population data and episode data are power transformed.

Claim 1 further recites:

“(f) for each transformed population data record, standardizing each transformed population data record using the set of all transformed population data records as a first baseline to generate a corresponding standardized transformed population data record;

(g) for each transformed encounter data record, standardizing each transformed encounter data record using the set of all transformed encounter data records as a second baseline to generate a corresponding standardized transformed encounter data record;”

The specification discloses (page 7):

Next, the transformed values are scaled by the standard deviations, resulting in standardized values:

$$D_i = \text{sign}(\lambda_1) D_i^{\lambda_1}$$

$$P_i = \text{sign}(\lambda_2) P_i^{\lambda_2}$$

where

$$\text{sign}(\lambda_i) = \begin{cases} +1 & \text{if } \lambda_i \geq 0 \\ -1 & \text{otherwise} \end{cases}$$

Accordingly, the values are standardized.

Claim 1 further recites:

“(h) linking each standardized transformed encounter data record to a corresponding standardized transformed population data record;”

The specification discloses (page 7):

{0020} Then the two measures in each distance and population pair are weighted and summed to produce an intermediate provisional distance index.

The specification discloses that the distance and population values are paired.

Claim 1 further recites:

“(i) for each standardized transformed encounter data record, calculating a distance index based on the respective standardized transformed encounter data record and the corresponding standardized transformed population data record;

(j) for each distance index, standardizing the respective distance index using the set of all distance indices as a third baseline to generate a standardized distance index;”

The specification discloses (page 8):

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given a positive weight to ensure that the index will increase with increasing distance from the source of care services. And the population metric is given a negative weight to insure that the index will decrease as population or population density increase. Using the weighting in the preferred embodiment, the distance index for the  $i^{\text{th}}$  episode is denoted  $I_i$ :

$$I_i = \left( \frac{1}{2} \right) \left[ \exp(\alpha_1) \frac{D_i^{\beta_1}}{\text{std}(D^{\beta_1})} \right] - \left[ \exp(\alpha_2) \frac{P_i^{\beta_2}}{\text{std}(P^{\beta_2})} \right]$$

[0021] The  $I_i$  values are standardized, producing a scaled distance index for the  $i^{\text{th}}$  episode:

$$d_{\text{episode}(i)} = \frac{I_i - \text{mean}(I)}{\text{std}(I)}$$

Claim 1 further recites:

“(k) assessing the departure of the set of one or more standardized distance indices from a standard normal statistical distribution;

(l) if the assessment in step (k) conforms to a predetermined threshold, identifying the set of standardized distance indices as the set of optimized distance indices;

(m) else if the assessment in step (k) does not conform to the predetermined threshold, changing the one or more statistical parameters and repeating steps (d-k);”

The specification discloses (page 8):

[0021] The  $l_i$  values are standardized, producing a scaled distance index for the  $i^{\text{th}}$  episode:

$$d_{\text{episode}(i)} = \frac{l_i - \text{mean}(l)}{\text{std}(l)}$$

The Anderson-Darling metric is calculated for the distribution of distance values, to assess departure from a normal curve, and if the value of  $A_n^2$  is greater than or equal to  $A_{n,\alpha}^2$  then the null hypothesis of normality is rejected and values of  $\lambda_1$  and  $\lambda_2$  are incremented and the loop processing is repeated. Iterations continue until  $A_n^2$  is less than  $A_{n,\alpha}^2$ .

The specification discloses that the values are assessed for conformity with a predetermined parameter, and if not, the loop is repeated with a new parameter.

Claim 1 further recites:

“(n) identifying one or more health care providers;

(o) for each optimized distance index, risk-adjusting the respective optimized distance index and assigning the risk-adjusted optimized distance index to a single health care provider chosen from the set of one or more health care providers based on the geographic location served by the health care provider; and

(p) for each health care provider, generating a report by aggregating any risk-adjusted optimized distance indices assigned to the respective health care provider, wherein the report assesses for the corresponding geographic location served by the health care provider:

- (1) quality of health services;
- (2) under-resourced health care needs;
- (3) prevention of medical complications; and

(4) comparative performance of the corresponding health care providers to other health care providers.”

The specification discloses (page 8):

[0022] Risk-adjustment of indicator incidence rates may follow any of the methods known to those experienced in the art. The risk-adjustment must then be validated according to accepted statistical practices before interpretations and conclusions are drawn, or before the optimized values for  $\lambda_1$  and  $\lambda_2$  are deployed in a public health decision support software system.

The specification further discloses (page 3):

[0010] Although other factors outside the direct control of the health care system, such as poor environmental conditions or lack of patient adherence to treatment recommendations, can result in hospitalization, the indicators provide a meaningful starting point for assessing quality of health services in the community. Because the risk-adjusted indicators are calculated using readily available health system data, they are an easy-to-use and inexpensive screening tool. They can be used to provide a window into the community—to identify underserved or under-resourced community health care needs, to monitor how well complications from a number of common conditions are being avoided in the outpatient setting, and to compare performance of local health care systems across communities.

Accordingly, the risk-adjusted values may be used to generate a plurality of reports that can shed light into the particular performance levels of the health care provider.

Based on at least the evidence above, Examiner believes that claim 8 as currently pending is fully supported by a single embodiment in the specification as originally filed on 02/11/2003.

As such, the claim is given a priority date of 02/11/2003.

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance:

The primary reason for the allowance of claim 8 is the combination of the following limitations in the combination as recited and not found in the closest available prior art of record:

“(b) receiving an encounter dataset comprising one or more encounter data records, wherein each encounter data record describes a distance, measured in physical distance or time, between:

(1) an inception of a clinical event or need for care; and

(2) provision of care at an appropriate location of service;”

“(d) for each population data record, statistically power transforming the data contained in the respective population data record using the one or more statistical parameters to generate a corresponding transformed population data record;”

“(i) for each standardized transformed encounter data record, calculating a distance index based on the respective standardized transformed encounter data record and the corresponding standardized transformed population data record;

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(j) for each distance index, standardizing the respective distance index using the set of all distance indices as a third baseline to generate a standardized distance index;”

“(o) for each optimized distance index, risk-adjusting the respective optimized distance index and assigning the risk-adjusted optimized distance index to a single health care provider chosen from the set of one or more health care providers based on the geographic location served by the health care provider;”

The closest available prior art of record are as follows:

Seare (5557514) teaches using historical billing to rate a health care provider based on other providers' performance (Abstract and throughout).

Although Seare teaches analyzing the quality of service, Seare does not teach analyzing the level of service based on the recited technique. In particular, the specific statistical analysis is not taught in Seare.

Weinert (MSU Rurality index: development and evaluation, copy provided by Applicant on 07/10/2007) teaches a similar technique to calculate the rurality index.

In particular, Weinert teaches (page 455):

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The MSU Rurality Index represents an attempt to surmount the preceding three problems. First, the MSU Rurality Index is a quantitative index that assigns a value (degree of rurality) to each family on the urban/rural continuum and avoids artificial categorization. Second, the MSU Rurality Index is a family-based rather than a county-based measure, and thus residents within a county are not assumed to be equal on the urban/rural continuum. Third, this new index is locally normed. That is, the index is normed with respect to the subset of the population under study. Thus, as a research instrument, the index can discriminate among study participants even if they are relatively homogeneous with respect to the urban/rural dimension, e.g., all the study participants live in sparsely populated western states.

According to Weinert, the MSU Rurality Index is family-based.

This is wholly different than the claimed invention, which calculates the rurality index based on episodes rather than families.

Therefore, the claimed invention provides a different way to calculate a rurality index that provides advantages (e.g. being episode-based eliminates family biases of the MSU technique) not found in the prior art.

A search of foreign patents was also conducted; however, no relevant art was found.

Based on the best available prior art of record, nothing in the prior art anticipates or otherwise renders the claimed invention obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/T. N./

Examiner, Art Unit 3626

08/29/2009

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626